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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/564,360	03/02/2006	Peter Neuenschwander	126402	9404

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EXAMINER	
DOLLINGER, MICHAEL M	
ART UNIT	PAPER NUMBER
1796	
MAIL DATE	DELIVERY MODE
11/09/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/564,360	NEUENSCHWANDER, PETER	
	Examiner	Art Unit	
	MIKE DOLLINGER	1796	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 August 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *19-36* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *19-36* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Specification

1. The objection to the specification is withdrawn.

Claim Objections

2. The claims objections have been obviated by the amendment to claim 34 as well as Applicant's arguments filed 08/03/2009.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

1. Claims 19-29 and 31-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Neuenschwander et al (US 5,665,831, hereinafter referred to as '831) in view of Hori et al (US 5,840,811).

2. '831 discloses biocompatible block copolymers built up from at least three components and has at least two chemically different block units which are α,ω-dihydroxypolyester or α,ω-dihydroxypolyether joined to one another by means of a diisocyanate, a diacid halide or a phosgene by linear polycondensation [2:9-17]. One of the block units is an α,ω-dihydroxypolyester obtained be transesterification of poly-(R)-(3)-hydroxybutyric acid, or copolymers thereof with 3-hydroxyvaleric acid with ethylene

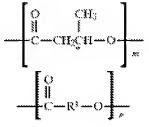
glycol [2:21-25]. The copolymers of 3-hydroxyvaleric acid include 3-(R)-hydroxyvaleric acid [14:58-60]. The α,ω-dihydroxypolyethers include poly(tetrahydrofuran) (or poly(oxytetramethylene)) [14:5-15] and α,ω-dihydroxypoly(oxyethylene-co-oxypropylene) [claim 7]. The block copolymers are biodegradable *in vivo* [11:20-21], can be melt processed [claim 17] and can comprise other co-condensed low molecular weight compounds having one or more functional groups [8:11-24] which may allow covalent bonding of active compounds such as diagnostics and pharmaceutically active compounds [8:44-48]. The block copolymers may be used for medical implants [9:42-44] which can be in the form of a tube optionally with several channels [9:54-57]. The block copolymer may also have a porous structure for the medical implant [9:60-62]. The block copolymer can also be a surgical aid intended for use in or on the body [claim 24].

3. Regarding claim 20, inventive example 23 discloses a biocompatible block copolymer having the formula poly(poly(.alpha.,.omega.-dihydroxy-poly(3(R)-hydroxybutyrate)-ethylene-poly(3-(R)-hydroxybutyrate))-alt-2,2,4-trimethylhexamethylene-1,6-diisocyanat e)-co-poly(.alpha.,.omega.-dihydroxy-(oligo(glycolide-block-.epsilon.-capro lactone)-ethylene-oligo(glycolide-block-.epsilon.-caprolactone))-alt-2,2,4- trimethylhexamethylene-1,6-diisocyanate)) [22:29-35].

4. Regarding claim 36, the α,ω-dihydroxy-(oligo(3-(R)-hydroxybutyrate-ethylene-oligo-(3-(R)-hydroxybutyrate)) prepared by transesterification of poly((R)-3-hydroxybutyrate) with ethylene glycol is dissolved in methylene chloride in order to be purified by filtration and chromatography [11:56-60].

5. '831 do not disclose the α,ω-dihydroxy-(oligo(3-(R)-hydroxybutyrate)-ethylene-oligo-(3-(R)-hydroxybutyrate)) reacted with a compound selected from the group consisting of a diglycolide, a dilactide, a caprolactone or mixtures thereof.

6. Hori et al discloses an optically active block polyester copolymer formed of structural units represented by the formulae:



(I)

(II)

[abstract].

The monomer of formula (I) may be (R)-β-butyrolactone and (S)-β-butyrolactone [4:42-44] and the monomer of formula (II) may be glycolide [5:8; Example 17], lactide [5:8], ε-caprolactone [5:9], and combinations of two or more [5:23-24]. The copolymerization is carried out in the presence of a catalyst [abstract]. Hori et al teach that the addition of a the specified lactones to the optically active butyrolactone provides a copolymer excelling in biodegradability and hydrolyzability, possessing a high molecular weight and a melting point sufficiently high to tolerate the conditions of practical use, and serving as a high strength material [3:19-25].

7. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have prepared a biodegradable block copolymer by reacting an (R)-3-hydroxybutyrate polyester with a diglycolide, dilactide or caprolactone because '831 teach that it is within the skill of the art to prepare a biodegradable block copolymer from an (R)-3-hydroxybutric acid and other macrodiols and Hori et al teach that it is

within the skill of the art to copolymerize (R)-3-hydroxybutyrolactone with a glycolide, lactide or caprolactone. One would have been motivated to copolymerize the (R)-3-hydroxybutric acid of '831 with one of these lactones because Hori et al teach that it provides a copolymer with excellent biodegradability and hydrolyzability, possessing a high molecular weight and a melting point sufficiently high to tolerate the conditions of practical use, and serving as a high strength material. Absent any evidence to the contrary, there would have been a reasonable expectation of success in modifying the (R)-3-hydroxybutyrate of '831 with a glycolide, lactide or caprolactone to achieve superior resin properties.

8. Claims 19, 21-29 and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Neuenschwander et al (US 5,665,831, hereinafter referred to as '831) in view of Tokiwa et al (US 5,124,371).

9. '831, discussed above, do not disclose the α,ω-dihydroxy-(oligo(3-(R)-hydroxybutyrate)-ethylene-oligo-(3-(R)-hydroxybutyrate)) reacted with a compound selected from the group consisting of a diglycolide, a dilactide, a caprolactone or mixtures thereof.

10. Tokiwa et al disclose the copolymerization of polycaprolactone (PCL) with poly-β-hydroxybutyrate (PHB) [1:35-40]. The copolymer is formed by copolymerization of PCL and PHB in the presence of a catalyst to allow transesterification between the PCL and PHB [2:21-26]. Tokiwa et al teach that PHB alone is very brittle due to its highly

crystalline structure but the blend/copolymer of PHB and PCL provides satisfactory physical properties while maintaining biodegradability [1:47-53].

11. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have prepared a biodegradable block copolymer by reacting an (R)-3-hydroxybutyrate polyester with a caprolactone because '831 teach that it is within the skill of the art to prepare a biodegradable block copolymer from an (R)-3-hydroxybutric acid and other macrodiols and Tokiwa et al teach that it is within the skill of the art to copolymerize poly-β-hydroxybutyrate with a polycaprolactone. One would have been motivated to copolymerize the (R)-3-hydroxybutric acid of '831 with polylactone because Tokiwa et al teach that it provides a biodegradable copolymer with satisfactory physical properties compared to the highly brittle poly-β-hydroxybutyrate homopolymer. Absent any evidence to the contrary, there would have been a reasonable expectation of success in modifying the (R)-3-hydroxybutyrate of '831 with a polycaprolactone increase the toughness (reduce the brittleness) of the (R)-3-hydroxybutyrate segment of the biocompatible copolymer.

12. Claim 30 is rejected under 35 U.S.C. 103(a) as being unpatentable over Neuenschwander et al (US 5,665,831, hereinafter referred to as '831) in view of Hori et al (US 5,840,811) or Tokiwa et al (US 5,124,371) as applied to claim 19 above, and further in view of Williams et al (US 6,548,569 B1).

13. '831 does not disclose heart valves made from the biocompatible block copolymers. '831 does teach, however, that the biocompatible block copolymers may be made into porous structured medical implants [claim 21].

14. Williams et al teach that polyhydroxyalkanoate polymers, used alone or in combination with other materials, offer the necessary mechanical properties and bioabsorption profiles for tissue engineered heart valves from porous heart valve scaffolds [24:35-40]. Selection of a known material based on its suitability for its intended use is *prima facie* obvious, see *Sinclair & Carroll Co. v. Interchemical Corp.*, 325 U.S. 327, 65 USPQ 297 (1945). It would have been obvious to one having ordinary skill in the art at the time the invention was made to have prepared a heart valve from a biocompatible block copolymer comprising a polyhydroxyalkanoate block because '831 teaches that it is within the skill of the art to prepare a medical implant device with a porous structure from a biocompatible block copolymer and Williams et al teach that it is within the skill of the art to prepare a tissue engineered heart valves from porous polyhydroxyalkanoates. One would have been motivated to do this because Williams et al teaches that the polyhydroxyalkanoates possess the mechanical properties and bioabsorption profiles for tissue engineered heart valves. Absent any evidence to the contrary, there would have been a reasonable expectation of success in preparing a heart valve from the biocompatible block copolymers of '831 in view of Hori et al or Tokiwa et al.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

15. Claims 19 and 30 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-6 and 10 of copending Application No. 12/303,897. Although the conflicting claims are not identical, they are not patentably distinct from each other. It is clear that all the elements of the instant claims are to be found in the copending claims (as the instant claims fully encompass copending claims). The difference between the instant claims and the copending claims lies in the fact that the copending claims include more elements and are thus more specific. Thus the invention of copending claims is in effect a "species" of the "generic" invention of instant claims. It has been held that the generic invention is "anticipated" by the "species". See *In re Goodman*, 29 USPQ2d 2010 (Fed. Cir. 1993).

Since instant claims are anticipated by the copending claims, they are not patentably distinct from each other.

16. Examiner notes that the presently claimed diol corresponds to the copendingly claimed α,ω-dihydroxy-polyester (IV); the presently claimed α,ω-dihydroxypolyester component corresponds to the copendingly claimed diol (I); and the presently claimed α,ω-dihydroxypolyether component corresponds to the copendingly claimed α,ω-dihydroxy-polyether (III).

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

17. Claims 19, 20 and 31 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-6 and 10 of copending Application No. 12/302,995. Although the conflicting claims are not identical, they are not patentably distinct from each other. It is clear that all the elements of the instant claims are to be found in the copending claims (as the instant claims fully encompass copending claims). The difference between the instant claims and the copending claims lies in the fact that the copending claims include more elements and are thus more specific. Thus the invention of copending claims is in effect a "species" of the "generic" invention of instant claims. It has been held that the generic invention is "anticipated" by the "species". See *In re Goodman*, 29 USPQ2d 2010 (Fed. Cir. 1993). Since instant claims are anticipated by the copending claims, they are not patentably distinct from each other.

18. Examiner notes that the presently claimed diol corresponds to the copendingly claimed α,ω-dihydroxy-polyester (IV); the presently claimed α,ω-dihydroxypolyester component corresponds to the copendingly claimed diol (I); and the presently claimed α,ω-dihydroxypolyether component corresponds to the copendingly claimed α,ω-dihydroxy-polyether (III).

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Response to Arguments

19. Applicant's arguments, see sections I and II on pages 5-6, filed 08/03/2009, with respect to the objections of the specifications and claims have been fully considered and are persuasive. The objections of 02/02/2009 have been withdrawn.

20. Applicant's arguments filed 08/03/2009 have been fully considered but they are not persuasive.

21. In section III-A-1, Applicant argues that the presently claimed copolymers have exceptionally good biocompatibility and control over the degradability of the copolymers. It appears as though Applicant may be arguing that there are unexpected results. This argument is not convincing. A showing of unexpected results must be supported by experimental evidence and not merely arguments. Applicant is reminded that any showing of unexpected results must meet three criteria: 1) the experimental data must compare the claimed invention to the analogous invention of the prior art, 2) the

showing must be commensurate in scope with the present claims, and 3) the results must be, in fact, unexpected.

In section III-A-2, Applicant argues argue that Hori does not describe the diol recited in claim 19. Applicant argues that this is confirmed by the fact that the block copolymer degradation rate is different from the degradation rate of the diol described in Applicant's specification. This argument is not convincing. It is true that the claimed diol is not found in Hori. However Hori discloses a method of copolymerizing a butyrolactone diol with glycolide, lactide, ε-caprolactone or combinations of two or more. This modification to the polybutyrolactone diol of Neuenshwander would result in the diol of the claims. The test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981).

22. In section III-B, Applicant argues Tokiwa does not describe the claimed diol but rather a polycaprolactone/poly-beta-hydroxybutyrate copolymer. Applicant argues that Tokiwa does not describe the transesterification of the specific diol of the claims. This argument is not convincing. It is true that the claimed diol is not found in Tokiwa. However Tokiwa discloses a method of transesterifying a polycaprolactone (PCL) with poly-β-hydroxybutyrate (PHB) which leads to improved PHB compositions. This modification to the PHB diol of Neuenshwander would result in the diol of the claims.

The test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981).

23. In section III-C, Applicant argues that Williams describes biocompatible polyhydroxyalkanoate produced by an enzymatic process using recombinant bacteria which cannot produce the claimed copolymers. This argument is not convincing. The specific polymers of Williams are not included in the rejection of record. The specific polymers of Neuenschwander are combined with the heart valves of Williams to arrive at the claimed heart valves. The specific polymers of Williams are irrelevant to the *prima facie* case of obviousness.

24. Applicant argues that the obviousness type double patenting rejections should be withdrawn. Since the arguments directed toward the prior art rejections were not convincing, the double patenting rejections are maintained and held in abeyance.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within

TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MIKE DOLLINGER whose telephone number is (571)270-5464. The examiner can normally be reached on M-F 9-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Randy Gulakowski can be reached on 571-272-1302. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/mmd/

/Randy Gulakowski/
Supervisory Patent Examiner, Art Unit 1796